UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

KATHLENE A. PENICH GARROSS,
Plaintiff,

v. **Case No. 14-cv-0134**

MEDTRONIC, INC. and
MEDTRONIC SOFAMOR DANEK USA INC.,
Defendants.

DECISION AND ORDER

Plaintiff, Kathlene Penich Garross, brings this diversity suit against defendants (collectively "Medtronic") alleging numerous tort claims stemming from her spinal surgery. Specifically, plaintiff alleges that Medtronic violated state law by promoting an off-label use of a Class III medical device regulated by the Food and Drug Administration ("FDA"). Medtronic moves to dismiss the complaint on several grounds primarily that plaintiff's claims are expressly and impliedly preempted by federal law.

I. Background

The Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360c et seq., amended the Food, Drug and Cosmetic Act ("FDCA"), establishing several levels of federal oversight of medical devices. Class III devices receive the most oversight and require premarket approval by the FDA. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317–18 (2008). Manufacturers must submit a multi-volume premarket approval application specifying, among other things, the "intended use" of the device. 21 U.S.C. § 360e(c)(2)(A)(iv). The FDA then determines the safety and effectiveness of the device based "on the conditions of use included" in the application. § 360e(d)(1)(A). "Once a device has received premarket

approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design, specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Riegel*, 552 U.S. at 319. Such changes require the manufacturer to submit a supplemental application to the FDA, which is subject to the same rigorous standards of review as an initial premarket approval application. *Id.*

In 2002, the FDA granted premarket approval for Medtronic's Infuse bone graft/lt-cage lumbar tapered fusion device ("combination device"), a Class III device designed to treat degenerative disc disease which affects the spine. The device has two components: (1) a spinal fusion cage and (2) a bone graft component, which includes a genetically-engineered human protein and a sponge-like carrier or scaffold for the protein that is placed inside the cage. The FDA's premarket approval specified that the combination device could be used in the lumbar spine (L4-S1) via an anterior, or abdominal, approach, which was the intended use Medtronic supplied in its premarket approval application. The FDA has never approved use of the combination device in other parts of the body or in any other type of procedure. Further, it has never approved use of the bone graft component separate from the cage component. In fact, the FDA-approved labeling states that "[t]hese components must be used as a system. The InFUSE Bone Graft component must not be used without the LT-Cage Lumbar Tapered Fusion Device component." Defs.' Br. in Supp. Ex. 3, at 2 (ECF No. 16-3). The label goes on to explain that "[t]he safety and effectiveness of the InFUSE Bone Graft component with other spinal implants, implanted at locations other than the lower lumbar spine, or used in surgical techniques other than anterior open or anterior laproscopic approaches have not been established. When degenerative disc disease was treated by a posterior lumbar interbody fusion procedure with cylindrical

threaded cages, posterior bone formation was observed in some instances." *Id.* at 5.

In 2008, plaintiff had spinal surgery. Her surgeon implanted the Infuse bone graft component without the cage component at the L1-L2 vertebrae using a posterior approach. This was an "off-label" use of the device for several reasons: it involved only one component rather than the combination device as a whole, it was implanted in the spine at a different location than that approved, and it relied on a posterior rather than an anterior approach. Since her 2008 surgery, plaintiff alleges that she has experienced "exuberant bone growth," causing pain and requiring additional surgeries, which she attributes to the off-label surgery. Compl. at 4 (ECF No. 1).

Despite the label warnings and the limited nature of the premarket approval, plaintiff alleges that Medtronic promoted the type of off-label use used in her surgery, namely use of the bone graft component via a posterior approach, in violation of federal law. Specifically, she alleges that Medtronic paid opinion leaders in the medical community to promote riskier off-label uses of the bone graft component and to hide and downplay the risks of these off-label uses, discouraged publication of adverse events resulting from these off-label uses, and failed to report adverse events related to off-label uses to the FDA. She further alleges that these violations of federal law caused her injuries and constitute evidence of various state law torts such as fraudulent misrepresentation, fraud in the inducement, constructive fraud, strict products liability – failure to warn, strict products liability – design defect, breach of express and implied warranty, negligence, and negligent misrepresentation.

II. Discussion

A. Preemption

The FDCA expressly preempts any state or local requirement relating to medical devices that is "different from, or in addition to" federal requirements and that "relates to the safety or effectiveness of the device." 21 U.S.C. § 360k(a); *Riegel*, 552 U.S. at 316. To determine whether a federal law expressly preempts a state law claim, I first examine whether there are federal "requirements" applicable to the medical device. *Id.* at 321–22. If so, then I determine whether plaintiff's state common law claims are "different from, or in addition to" the federal requirements and related to the safety and effectiveness of the device. *Id.*

"The Supreme Court . . . has made clear that section 360k protects a medical device manufacturer from liability to the extent that it has *complied* with federal law, but it does not extend protection from liability where the claim is based on a *violation* of federal law." *Bausch v. Stryker Corp.*, 630 F.3d 546, 552 (7th Cir. 2010); *see also Riegel*, 552 U.S. at 330 (limiting its holding to claims that a device manufacturer "violated state tort law notwithstanding compliance with the relevant federal requirements"); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 513 (1996) (O'Connor, J., concurring in part and dissenting in part) ("I also agree [with the Court] that the [plaintiff's] claims are not pre-empted by § 360k to the extent that they seek damages for Medtronic's alleged violation of federal requirements."). This is so because a state law remedy for a violation of federal law does not impose a requirement "different from, or in addition to" a federal requirement; it simply gives manufacturers an additional reason to comply. *Lohr*, 518 U.S. at 513 (O'Connor, J.

concurring in part and dissenting in part) ("Section 360k does not preclude States from imposing different or additional *remedies*, but only different and additional *requirements*."); *Bausch*, 630 F.3d at 553 ("[I]f [plaintiff] can prove those allegations of harm caused by violations of federal law, her claims under state law would not impose on defendants any requirement 'different from, or in addition to, any requirement' imposed by federal law."); *id.* ("Just as a plaintiff in an auto accident may use the other driver's speeding violation as evidence of negligence, plaintiff . . . claims that she was injured by [defendant's] violations of federal law.").

In addition to express preemption, plaintiff's state law claims must survive implied preemption, a doctrine under which state law claims arising "solely from the violation of [federal] requirements" are impliedly preempted. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352–53 (2001) (finding that a state claim for "fraud on the FDA" was a claim solely for violation of federal law impliedly preempted by 21 U.S.C. § 337(a)). Thus, there is a gap through which plaintiff's state law claims must fit if they are to escape express and implied preemption: "The plaintiff must be suing for conduct that *violates* the Food, Drug, and Cosmetic Act (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the Food, Drug, and Cosmetic Act (such a claim would be impliedly preempted under *Buckman*)." *Bausch*, 630 F.3d at 557–58 (quoting *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010)). In other words, a state law claim which alleges a violation of the FDCA but which alleges that violation in the context of an independent, "well-recognized duty owed to [plaintiff] under state law" can survive both express and implied preemption. *Id.* at 558.

First, I consider whether federal requirements applicable to the device exist. Premarket approval of Class III devices impose federal "requirements" within the meaning of § 360k(a). *Riegel*, 552 U.S. at 322–23. These requirements are device-specific, not use-specific, *Ramirez v. Medtronic, Inc.*, 961 F. Supp. 2d 977, 987–88 (D. Ariz. 2013), and thus are still applicable to the device even for off-label uses. Thus, federal requirements applicable to the Infuse combination device exist. Plaintiff contends, however, that no federal requirements apply to the bone graft component itself because premarket approval applied only to the use of the components together. I need not decide this issue because even assuming federal requirements exist, the state law on which plaintiff's claims rely do not place different or added requirements on defendants and are thus not expressly preempted.

Each of plaintiff's claims is based on an alleged underlying violation of federal law. First, her fraudulent misrepresentation and fraud in the inducement claims are based on Medtronic's alleged promotion of off-label uses of the bone graft component, including misrepresenting the risks of such off-label uses to the medical community. While the FDCA does not regulate a doctor's off-label use of a device, *see Buckman*, 531 U.S. at 350–52, the FDA prohibits device manufacturers from promoting off-label uses of their products, *see* 21 U.S.C. § 331(a) (prohibiting manufacturers from misbranding medical devices); 21 C.F.R. § 814.80 (providing that a "device may not be . . . advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device"); *Carson v. Depuy Spine, Inc.*, 365 Fed. Appx. 812, 815 (9th Cir. 2010) ("[W]hile doctors may use a drug or device off-label, the marketing and promotion of a Class III

device for an unapproved use violates Section 331 of the FDCA.").[1] Citing these alleged violations of federal law as evidence of fraudulent misrepresentation and fraud in the inducement thus does not impose requirements different from or in addition to federal requirements; rather state law merely imposes a remedy for such violations.

Second, plaintiff's negligence, negligent misrepresentation, strict liability – failure to warn, fraud, and constructive fraud claims are based on Medtronic's alleged failure to report adverse events to the FDA and to submit a supplemental application seeking approval of the off-label use it was promoting. Class III medical device manufacturers are required to report adverse events to the FDA, 21 C.F.R. § 803.50, investigate serious adverse events and submit follow-up reports, 21 C.F.R. § 803.56, and submit a supplemental application for approval of additional uses of a medical device. 21 C.F.R. § 814.39 (listing "new indications for use of the device" as a change requiring supplemental FDA approval). Plaintiff may rely on these alleged violations as evidence that Medtronic violated a state common law duty to warn patients of the risks of the off-label use. Plaintiff does not claim that state law imposes an additional requirement on Medtronic to warn patients directly, but rather that a breach of these various federal requirements alone is

[1] Medtronic cites *U.S. v. Caronia*, 703 F.3d 149 (2d Cir. 2012) to support the assertion that "whether federal law prohibits off-label promotion remains a disputed question." Defs.' Br. in Supp., at 15 n.14 (ECF No. 16). While *Caronia* "construe[d] the FDCA as not criminalizing the simple promotion of a drug's off-label use because such a construction would raise First Amendment concerns," *Caronia*, 703 F.3d at 160, Medtronic has not raised First Amendment issues here, and I find those cases interpreting the statutes and federal regulations as prohibiting off-label promotion persuasive. *See, e.g.*, *Carson*, 365 Fed. Appx. at 815, *Houston v. Medtronic, Inc.*, 957 F. Supp. 2d 1166, 1179 (C.D. Cal. 2013); *Ramirez*, 961 F. Supp. 2d at 990 & n.8; *Hornbeck v. Medtronic, Inc.*, No. 13-C-7816, 2014 WL 2510817, at *4 (N.D. Ill. June 2, 2014).

enough to establish liability under her various common law claims.

Third, plaintiff's strict liability – design defect claim is based on Medtronic's alleged promotion of off-label use, failure to investigate and report adverse events, and failure to seek supplemental FDA approval of that off-label use. Plaintiff argues that Medtronic's device was defectively designed for the use Medtronic promoted, and that Medtronic's alleged violations of federal law in failing to seek supplemental FDA approval and promoting off-label use, despite knowledge of adverse effects, is evidence supporting her design defect claim. Again, the state law on which plaintiff relies does not impose a requirement different from or in addition to federal requirements; it merely creates a state law remedy.

Thus, none of plaintiff's state law claims are expressly preempted.

Nor are plaintiff's claims impliedly preempted. This is so because none of them arise solely from a violation of federal law; rather, each arises from an independent, well-recognized duty owed under state law. *See Buckman*, 531 U.S. at 353 (distinguishing between claims arising "from the manufacturer's alleged failure to use reasonable care" and claims arising "solely" from a violation of a federal requirement); *Bausch*, 630 F.3d at 558 (holding that claims which allege a "breach of a well-recognized duty owed to [plaintiff] under state law" are not impliedly preempted).[2]

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[2] Medtronic's alleged off-label promotion of its Infuse device has been the subject of litigation throughout the country, and some courts have concluded that claims similar to those asserted here are expressly and/or impliedly preempted. I do not find these cases persuasive. Moreover, I am bound by Seventh Circuit case law stating that "[t]he idea that Congress would have granted civil immunity to medical device manufacturers for their violations of federal law that hurt patients is, to say the least, counter-intuitive." *Bausch*, 630 F.3d at 549; *see also Hornbeck v. Medtronic, Inc.*, No. 13-C-7816, 2014 WL 2510817, at *4 (N.D. Ill. June 2, 2014) (noting that "*Bausch* makes clear that . . . a

B. Other Arguments for Dismissal

Medtronic makes several additional arguments, first that plaintiff's claims are time-barred by the applicable three year statute of limitations. *See* Wis. Stat. §§ 893.04, 892.54. In Wisconsin, claims begin to accrue "once a person either discovers the injury or in the exercise of reasonable diligence should have discovered the injury." *Claypool v. Levin*, 209 Wis. 2d 284, 301 (1997). "[D]iscovery occurs when a potential plaintiff has information that would give a reasonable person notice of her injury or its cause." *Id.* at 300. When a plaintiff should have reasonably discovered her injury is a fact issue. *Hennekens v. Hoerl*, 160 Wis. 2d 144, 172 (1991) (Abrahamson, J. dissenting); *Carlson v. Pepin Cnty.*, 167 Wis. 2d 345, 349 (Ct. App. 1992).

Generally, a statute of limitations bar is an affirmative defense, and it is "irregular" to dismiss a claim as untimely on a motion to dismiss. *Hollander v. Brown*, 457 F.3d 688, 691 n.1 (7th Cir. 2006) (quoting *United State v. N. Trust Co.*, 372 F.3d 886, 888 (7th Cir. 2004)). Under Fed. R. Civ. P. 8, a complaint need not anticipate or overcome affirmative defenses such as the statute of limitations. *Xechem, Inc. v. Bristol-Myers Squibb Co.*, 372 F.3d 899, 901 (7th Cir. 2014). Dismissal based on a statute of limitations under Rule 12(b)(6) is only appropriate when the plaintiff effectively pleads herself out of court by alleging facts that are sufficient to establish the defense. *Hollander*, 457 F.3d at 691 n.1.

Here, plaintiff's complaint alleges that she "did not known[sic] and could not have known by the exercise of reasonable diligence, until September 11, 2012" of her injuries.

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medical device manufacturer receives no protection where a plaintiff can prove that the manufacturer's violation of federal law caused his or her injury compensable under state law").

Compl., at 15 (ECF No. 1). This is enough to survive defendant's motion to dismiss. When plaintiff should have discovered her injuries is a fact question best determined after discovery.

Second, Medtronic argues that plaintiff's failure to warn and negligence claims fail as a matter of law. It contends that under the learned intermediary doctrine, its duty to warn runs to the surgeon and not the patient, and that under the sophisticated user doctrine, it has "no duty to warn members of a trade or profession about dangers generally known to the trade or profession." *Haase v. Badger Mining Corp.*, 266 Wis. 2d 970, 984 (Ct. App. 2003) (internal quotations omitted). Even assuming that the learned intermediary doctrine applies in Wisconsin, which plaintiff contests, I decline to dismiss plaintiff's failure to warn claims at this time. Plaintiff alleges that Medtronic intentionally misrepresented and misled the medical community about the risks associated with the promoted off-label use of the Infuse bone graft component. These allegations raise a fact issue as to whether the sophisticated user doctrine applies and precludes dismissal.

Third, Medtronic argues that plaintiff fails to adequately plead failure to warn, negligence, design defect, and failure to report adverse events. To survive, plaintiff's complaint must "state a claim to relief that is plausible on its face," *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007), and must give Medtronic fair notice of the nature of her claims. *Bausch*, 630 F.3d at 559. Generally, "notice pleading remains the standard." *Id.* (internal quotations omitted). Plaintiff's claims are sufficiently pled to survive Medtronic's motion to dismiss. While Medtronic complains of an absence of detail, "much of the product-specific information about manufacturing needed to investigate" claims such

as plaintiff's "is kept confidential by federal law." *Id.* at 558. Thus, "[f]ormal discovery is necessary before a plaintiff can fairly be expected to provide a detailed statement of the specific bases for her claim." *Id.*

Fourth, Medtronic argues that plaintiff fails to plead fraud with particularity as required by Fed. R. Civ. P. 9(b). Rule 9(b) requires a plaintiff to plead "the who, what, when, where, and how" of the allegedly fraudulent act. *Wigod v. Wells Fargo Bank, N.A.*, 673 F.3d 547, 569 (7th Cir. 2012) (internal quotations omitted). Plaintiff satisfies this standard. Her complaint alleges the who (Medtronic in conjunction with various "opinion leaders"), the what (promoting off-label use of the Infuse bone graft component and causing plaintiff's injury), the when (after premarket approval of the Infuse combination device in 2002, continuing after a DOJ settlement in 2006, and through the time of plaintiff's surgery), the where (in various places, including editorials and industry-sponsored articles), and the how (by paying "opinion leaders" to promote the off-label use and manipulating medical literature). This is sufficient.

Finally, plaintiffs allege that Medtronic breached express and implied warranties, and Medtronic moves to dismiss these claims on a variety of grounds. Plaintiff failed to respond to Medtronic's arguments. Failure to respond to an argument results in waiver. *Bonte v. U.S. Bank, N.A.*, 624 F.3d 461, 466 (7th Cir. 2010); *Kirksey v. R.J. Reynolds Tobacco Co.*, 168 F.3d 1039, 1041 (7th Cir. 1999) ("If [judges] are given plausible reasons for dismissing a complaint, they are not going to do the plaintiff's research and try to discovery whether there might be something to say against the defendants' reasoning."). Thus, I will dismiss plaintiff's warranty claims.

C. Request for Judicial Notice

Finally plaintiff requests that I take judicial notice of several medical journal articles, a U.S. Senate staff report, hearing transcripts and filings from other cases, the FDA-approved labeling for the Infuse combination device, and letters from Senators to Medtronic. Medtronic asks me to take judicial notice of the FDA-approved labeling but objects to my taking judicial notice of the articles, staff report, and Senator letters and to accepting the factual findings in any case materials. I may take judicial notice of publicly-available documents when the contents are "not subject to reasonable dispute" and are "capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned." Fed. R. Civ. P. 201(b). Neither party disputes the accuracy of the FDA-approved labeling, and the document is publicly available on the FDA's website. *See Funk v. Stryker Corp.*, 631 F.3d 777, 783 (5th Cir. 2011) (affirming the district court's decision to take judicial notice of the FDA's premarket approval of a medical device). Thus, I will take judicial notice of the FDA-approved labeling. I will deny plaintiff's request for judicial notice as to the rest of the documents because I did not rely on them in reaching my decision.

III. Conclusion

THEREFORE, IT IS ORDERED that defendants' motion to dismiss (ECF No. 15) is **GRANTED** in part and **DENIED** in part.

(a) The motion is **GRANTED** as to plaintiff's breach of express and implied warranty claims;

(b) The motion is **DENIED** as to all other claims.

Dated at Milwaukee, Wisconsin, this 21st day of January, 2015.

s/ Lynn Adelman

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LYNN ADELMAN
District Judge